

Title

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Certificate of Analysis Finished Product

Product Name	HYDRALZIN 20 Injection	A.R. No.	NL/FP/25/210
Generic Name	Hydralazine Hydrochloride Injection USP 1ml	Sampled qty.	60 Ampoules
Batch No.	A25178A	Sampled by	Dhananjay
Batch Size	19,990 Ampoules	Sampled on	04/10/2025
Mfg. Date	08/2025	Date of Testing	04/10/2025
Exp. Date	07/2027	Date of Release	23/10/2025

S. No.	Tests	Specifications	Observations		
1.	Description	A clear colourless solution filled in amber colour glass ampoule.	A clear colourless solution filled in amber colour glass ampoule.		
2.	Identification (by IR)	The IR absorption spectrum of a potassium bromide dispersion of the residue so obtained exhibits maxima only at the same wavelengths as those of USP Hydralazine Hydrochloride RS similarly treated and prepared.	Complies		
3.	Nominal fill volume	NLT 1ml	1.0 ml		
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	1.1 ml		
5.	pH	3.4 to 4.4	3.94		
6.	Particulate Matter (A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visual Particle	NMT 6000/Ampoule NMT 600/ Ampoule The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be seen with naked eye.	156/Ampoule 4/Ampoule Complies		
7.	Bacterial Endotoxins	NMT 1.45 USP EU/mg.	Less than 1.45 USP EU/mg.		
8.	Sterility	No microbial growth should be observed.	Complies		
9.	Assay: (By Titration) Each ml contains:				
Ingredients		Labeled claim	Found	% of labeled amount	Limits % of labeled amount
Hydralazine Hydrochloride USP		20 mg	20.702 mg	103.51%	95.0% to 105.0%

Remarks: In the opinion of the undersigned the sample referred to above is/is ~~not~~ of the standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/~~not~~ complies as per IP/BP/USP/HS.

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